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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,814	06/04/2007	Steven S. Bondy	50304/128001	4926

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

RAHMANI, NILOOFAR

ART UNIT	PAPER NUMBER
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1625

NOTIFICATION DATE	DELIVERY MODE
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02/11/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No. 10/583,814	Applicant(s) BONDY ET AL.	
	Examiner NILOOFAR RAHMANI	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/02/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 72-90 are currently pending in the instant application and claims 1-71 are cancelled.

Priority

2. This application was filed on 06/04/2007, and is a 371 of PCT/US04/43112, filed on 12/21/2004, and claims benefit of 60/532,292, filed on 12/22/2003, and claims benefit of 60/533,963, filed on 01/02/2004, and claims benefit of 60/591,069, filed on 07/26/2004, and claims benefit of 60/591,024, filed on 07/26/2004, and claims benefit of 60/590,989, filed on 07/26/2004, and claim benefit of 60/590,990, filed on 07/26/2004.

3. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 76, 78 and 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 76, 78 and 80 are rejected because the term “examples 102, 103, 106, 315, 16, 30, 42, 318, 2to 15, 17 to 29, 31, 41, 43 to 101, 104, 105, 107 to 314, 316, 317, and 319 to 379” is confusing. What are “examples 102, 103, 106, 315, 16, 30, 42, 318, 2to 15, 17 to 29, 31, 41, 43 to 101, 104, 105, 107 to 314, 316, 317, and 319 to 379”? Correction is required.

4. Claims 74-75, 79 are rejected because the term "Q is a bond or a linking group connecting M to R³ and having 1-10 atoms" are confusing. What is the definition for "Q" and what are the "linking group"? Correction is required.

5. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 74-75, 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification lacks enablement of the term "Q is a bond or a linking group connecting M to R³ and having 1-10 atoms", which are claimed in the compound claims. While enabling for some linking group examples such as alkylene, which are on pages 88-238 of the instant specification, it is not seen where this enables other types of linking groups. Therefore, the specification lacks enablement for the term "Q is a bond or a linking group connecting M to R³ and having 1-10 atoms" in the instant specification.

6. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 72-90 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making solvates and hydrates of the claimed compounds. The specification does not enable any person skilled in the art of synthetic organic chemistry to make the invention commensurate in scope with these claims. "The factors to be considered [in making an enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims", *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. a) Determining if any particular substrate would form a solvate or hydrate would require synthesis of the substrate and subjecting it to recrystallization with a variety of solvents, temperatures, pressures, and humidity. The experimentation is potentially open-ended. b) The direction concerning the solvates is found on pages 61-62, which simply states Applicants intent to make them. c) There is no working example of any hydrate or solvate formed. The claims are drawn to solvates, yet the numerous examples presented all failed to produce a solvate.

These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here. There is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

d) The nature of the invention is chemical synthesis, which involves chemical reactions. e) The state of the art is that is not predictable whether solvates will form or what their composition will be. In the language of the physical chemist, a solvate of organic molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Solid State Chemistry). West, Anthony R., "Solid State Chemistry and its Applications, Wiley, New York, 1988, pages 358 & 365. The solvent molecule is a species introduced into the crystal and no part of the organic host molecule is left out or replaced. In the first paragraph on page 365, West (Solid State Chemistry) says, "it is not usually possible to predict whether solid solutions will form, or if they do form what is their compositional extent". Thus, in the absence of experimentation one cannot predict if a particular solvent will solvate any particular crystal. One cannot

predict the stoichiometry of the formed solvate, i.e. if one, two, or a half a molecule of solvent added per molecule of host. In the same paragraph on page 365 West (Solid State Chemistry) explains that it is possible to make meta-stable non-equilibrium solvates, further clouding what Applicants mean by the word solvate. Compared with polymorphs, there is an additional degree of freedom to solvates, which means a different solvent or even the moisture of the air that might change the stable region of the solvate. f) The artisan using Applicants invention to prepare the claimed compounds would be a process chemist or pilot plant operator with a BS degree in chemistry and several years of experience. g) Chemical reactions are well-known to be unpredictable, *In re Marzocchi*, 169 USPQ 367, *In re Fisher*, 166 USPQ 18. h) The breadth of the claims includes all of the thousands of compounds of formula *** as well as the presently unknown list of solvents embraced by the term "solvate".

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

7. Claim Rejections - Obvious Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute)

so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 168 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 72-90 are rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over the claims 1-2, 5 of the Bondy et al., US 2006/0252791. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention embraces the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Bondy et al. claimed analogues compounds and composition in claims 1-2 and 5 as the instant claims 72-90.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the issued claims is the claims are not word for word identical but the scope of both sets of claims overlaps mostly significantly with each other.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

The issued claims 1-2 and 5 are therefore fully embraced by the instant claims 72-90.

8. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

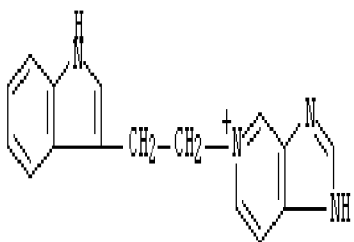
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 77-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Grazul et al., Natural Product Letters (1994), 5(3), 187-95. Grazul et al. discloses the instant claimed compound, which from the STN search is

RN 161197-59-7

CN 3H-Imidazo[4,5-c]pyridinium, 5-[2-(1H-indol-3-yl)ethyl]-, bromide

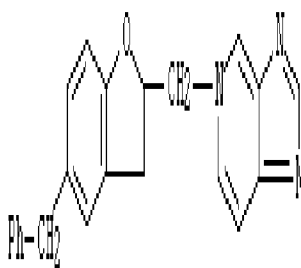


, which anticipates the instant compounds when X is C₁-C₁₀ alkylene, R³ is heterocycle, and R¹⁷ is hydrogen in the instant application. Therefore, the instant claims are anticipated by Grazul et al.

9. Claims 77-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandrakumar et al., US 5723492. Chandrakumar et al. discloses the instant claimed compound, which from the STN search is

RN 179022-94-7

CN 5H-Imidazo[4,5-c]pyridine, 5-[[2,3-dihydro-5-(phenylmethyl)-2-benzofuranyl]methyl]-



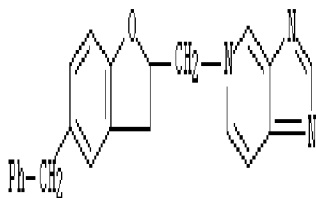
, which anticipates the instant compounds when X is C₁-C₁₀ alkylene, R³ is heterocycle, and R¹⁷ is aryalkyl in the instant application. Therefore, the instant claims are anticipated by Chandrakumar et al.

10. Claims 77-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandrakumar et al., US 5719306. Chandrakumar et al. discloses the instant claimed compound, which from the STN search is

RN 179399-04-3

CN 5H-Imidazo[4,5-c]pyridine, 5-[[2,3-dihydro-5-(phenylmethyl)-2-

benzofuranyl]methyl]-,

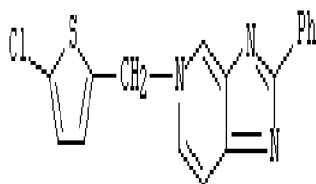


, which anticipates the instant compounds when X is C₁-C₁₀ alkylene, R³ is heterocycle, and R¹⁷ is aryalkyl in the instant application. Therefore, the instant claims are anticipated by Chandrakumar et al.

11. Claims 77-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Neyts et al., WO 2004005286. Neyts et al. discloses the instant claimed compound, which from the STN search is

RN 645420-73-1

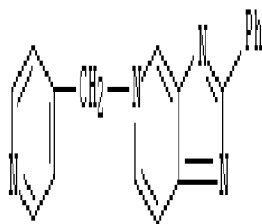
CN 5H-Imidazo[4,5-c]pyridine, 5-[(5-chloro-2-thienyl)methyl]-2-phenyl-



RN 645420-76-4

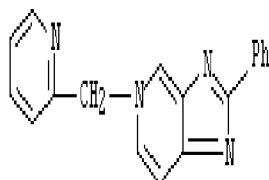
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CN 5H-Imidazo[4,5-c]pyridine, 2-phenyl-5-(4-pyridinylmethyl)-



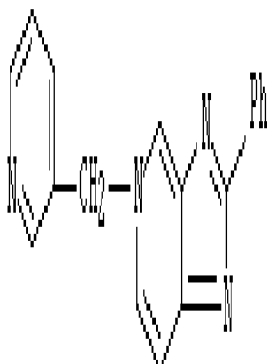
RN 645420-79-7

CN 5H-Imidazo[4,5-c]pyridine, 2-phenyl-5-(2-pyridinylmethyl)-



RN 645420-80-0

CN 5H-Imidazo[4,5-c]pyridine, 2-phenyl-5-(3-pyridinylmethyl)-



, which anticipates the instant compounds when X is C₁-C₁₀ alkylene, R³ is heterocycle, and R¹⁷ is hydrogen in the instant application. Therefore, the instant claims are anticipated by Neyts et al.

12. ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

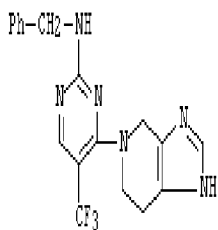
Claim 79 is rejected under 103(a) as being unpatentable over Cardozo et al., WO 2004067516.

Determination of the scope and content of the prior art (MPEP §2141.01)

Cardozo et al. disclosed analogous compounds, which from the STN search are

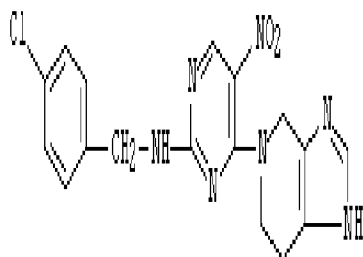
RN 736055-76-8

CN 2-Pyrimidinamine, N-(phenylmethyl)-4-(3,4,6,7-tetrahydro-5H-imidazo[4,5- c]pyridin-5-yl)-5-(trifluoromethyl)-



RN 736055-82-6

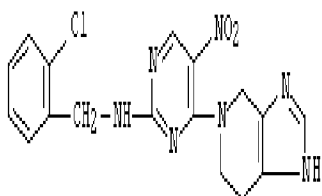
CN 2-Pyrimidinamine, N-[(4-chlorophenyl)methyl]-5-nitro-4-(3,4,6,7-tetrahydro- 5H-imidazo[4,5-c]pyridin-5-yl)-



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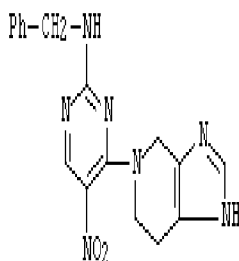
RN 736055-87-1

CN 2-Pyrimidinamine, N-[(2-chlorophenyl)methyl]-5-nitro-4-(3,4,6,7-tetrahydro-5H-imidazo[4,5-c]pyridin-5-yl)-



RN 736055-90-6

CN 2-Pyrimidinamine, 5-nitro-N-(phenylmethyl)-4-(3,4,6,7-tetrahydro-5H-imidazo[4,5-c]pyridin-5-yl)-



Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claim and the prior art compound is that the instant claim replaces one H of the prior art compound with a methyl.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the compounds of Cardozo et al. to obtain the instant claimed compounds.

A compound that differs only in molecular arrangement from the compounds disclosed in the prior art and which for which no unexpected

properties of this compound are disclosed in the specification is unpatenable, *Ex parte KRUEGER AND HAYES*, 121 USPQ 420, *In re NORRIS*, 84 USPQ 458, *In re Hass* 60 USPQ 552, which found a *prima facie* case of obviousness of 1-chloro-1-nitrobutane over 1-chloro-1-nitroisobutane taught in the prior art, *Ex parte Ulliyot*, 103 USPQ 185, which found a *prima facie* case of obviousness of 2-oxo-quinolines over a 1-oxo-isoquinoline taught in the prior art, *In re FINLEY*, 81 USPQ 383, which found a *prima facie* case of obviousness of 2-ethyl hexyl salicylate over octyl salicylate taught in the prior art.

Compounds that differ only by the presence or absence of an extra methylene group or two are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders *prima facie* obvious its homologues. The homologue is expected to be prepared by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing homologues. Of course, these presumptions are rebuttable by the showing of unexpected effects, but initially, the homologues are obvious even in the absence of a specific teaching to add or remove methylene groups. See *In re Wood*, 199 USPQ 137; *In re Hoke*, 195 USPQ 148, *In re Lohr*, 137 USPQ 548; *In re Magerlein*, 202 USPQ 473; *In re Wiechert*, 152 USPQ 249; *Ex parte Henkel*, 130 USPQ 474; *In re Fauque*, 121 USPQ; *In re Druey*, 138 USPQ 39.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is

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571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/NILOOFAR RAHMANI/

01/27/2009

/D. Margaret Seaman/

Primary Examiner, Art Unit 1625